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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/564,452
Filing Date: January 12, 2006
Appellant(s): AMMANN ET AL.

Gary M. Lobel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 22, 2010 appealing from the Office action mailed December 1, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-2 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spivey-Krobath et al. (WO 02/39834) in view of Brassart et al. (US 6,489,310).

Regarding claims 1-2, Spivey-Krobath et al. disclose a liquid or powdered reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) comprising a 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose 4.5 to 6g protein/100ml.

However, it is apparent that the instantly claimed amount of protein, i.e. 4.5 to 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so

close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructooligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including

both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would intrinsically possess the recited viscosity.

Regarding claim 8, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (p.7/L8-14, p.10/Table 1).

Regarding claim 9, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, Spivey-Krobath also disclose administering an effective amount of a powdered or liquid reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) comprising 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml

and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose 4.5 to 6g protein/100ml.

However, it is apparent that the instantly claimed amount of protein, i.e. 4.5 to 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructooligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would intrinsically possess the recited viscosity.

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Further, given that modified Spivey-Krobath et al. disclose method as presently claimed, it is clear that such method would intrinsically improve the digest tract and bowel function of a patient, inherently enhance mucosal barrier function in a patient, inherently promote gut health or comfort in an elderly patient, inherently maintain or restore a well-balanced gut flora, and intrinsically enhance mucosal function in a human individual.

Regarding claim 13, Spivey-Krobath et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition comprising 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary

fiber in an amount of 4 g. to about 50 g per 300 g of the composition to provide a liquid mixture (Abstract, p.3/L15-21, p.5/L5, p.8/L14-16, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose 4.5 to 6g protein/100ml.

However, it is apparent that the instantly claimed amount of protein, i.e. 4.5 to 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructooligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to prepared similarly to that presently claimed, it is clear that the composition would intrinsically possess the recited viscosity.

(10) Response to Argument

Summary

The Examiner submits that the primary reference in combination with the secondary reference, as relied up in the rejection, provide a proper *prima facie* case of obviousness, as stated in the Grounds of Rejection section, and would have placed the instantly claimed invention in the hands of the ordinarily-skilled artisan. In summary:

The instantly claimed invention is directed to:

(I) a nutritional composition having a viscosity of 30-80 mPas, and comprising (a) 4.5g to 6g protein/100ml composition; (b) a source of digestible carbohydrates; (c) a source of lipids; and (d) a source of dietary fiber wherein the dietary fiber, having an energy density of 1.3-1.8 kcal/ml, is in an amount of more than 2.5g/100ml and comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides;

(II) a method for improving digestive tract and bowel function, enhancing mucosal barrier function, maintaining or restoring a well-balanced gut flora, and promoting gut health or comfort in an elderly patient, the method comprising administering to a patient a nutritional composition of the present invention; and

(III) a method for preparing a nutritional composition, the method comprising: (a) mixing a liquid or powdered and reconstitutable nutritional composition according to the present

invention; and (b) hydrating the components to provide a liquid mixture with a viscosity of 30-80 mPas.

Spivey-Krobath et al. disclose a nutritional composition comprising (a) 7.0 or 10.5 g. protein/100 ml composition; (b) a source of digestible carbohydrates; (a) a source of lipids; and (d) a source of dietary fiber wherein the dietary fiber has an energy density of 1.6 kcal/ml, is in an amount of 4g to 50g/300 g of the composition and comprises 70% by weight fructooligosaccharide and 30% by weight inulin (i.e. soluble fiber) or a combination of fructooligosaccharide (i.e. soluble fiber) and acacia gum (i.e. soluble fiber) (Abstract, p.3/L15-17, p.5/L5-6, 35- p.6/L3, p.7/L8-14, p.8/L14-18, p.10/Table 1).

While **Spivey-Krobath et al.** does not explicitly disclose a protein content that overlaps with that presently claimed, the claimed range, i.e. 4.5g to 6.0g/100 ml composition, and the prior art range, i.e. 7.0g/100 ml composition, are close enough that one skilled in the art would have expected them to have the same properties (*see* MPEP 2144.05 – I. Overlap of Ranges).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). **Brassart et al.** teach that the fiber blend comprises 5-30% inulin (soluble dietary fiber), 10-40% fructooligosaccharides (i.e. oligosaccharide, soluble dietary fiber) and 20-50% pea outer fiber (i.e. non-soluble dietary fiber) (C4/L40-44). **Brassart et al.** teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, **Brassart et al.** teach that enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

It would have been obvious to one of ordinary skill in the art to have used a fiber blend including both soluble and insoluble fiber, as taught by **Brassart et al.**, in the nutritional composition of **Spivey-Krobath et al.** for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

Further, given **Spivey-Krobath et al.** disclose the interchangeability of soluble fibers, i.e. inulin and acacia gum in a nutritional composition (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified **Spivey-Krobath et al.** because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Spivey-Krobath et al. disclose a method for preparing a nutritional composition comprising the steps of blending the ingredients of the disclosed composition to provide a liquid mixture (Abstract, p.5/L35- p.6/L3, p.8/L14-18).

Spivey-Krobath et al. disclose administering an effective amount of the disclosed composition (Abstract, p.8/L1415).

Declaration under 37 C.F.R. §1.132-

Appellants explain that the consumption of high caloric and high nutrient compositions is problematic because they can cause gut pain or gut discomfort especially in patients with unbalanced gut flora and with gut impairment. Appellants allege unexpected results based on evidence submitted in a Declaration under 37 C.F.R. §1.132. First, Appellants explain that the Declaration summarizes a controlled study that demonstrates the surprising and unexpected tolerability (i.e. no reported negative effects or undesired abdominal symptoms) and low

viscosity of the presently claimed high fiber nutritional composition as compared to a similar composition having a lower amount of fiber.

Whether evidence shows unexpected results is a question of fact and the party asserting unexpected results has the burden of proving that the results are unexpected. *In re Geisler*, 116 F.3d 1465, 1469-70, 43 USPQ2d 1362, 1364-5 (Fed. Cir. 1997). One relying on data has a burden of not only establishing that unexpected results are actually obtained, but also the significance of those results to one of ordinary skill in the art. See *In Re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972) (inventor must show that the results claimed to be obtained with a claimed invention are actually obtained with the invention). The applicant has failed to meet their burden on several fronts.

First, while Appellants show that a composition comprising 2.6g/100ml dietary fiber (i.e. Clinutren® 1.5 Fiber-see Exhibit 3) is as tolerable as a similar low fiber composition (i.e. 0.5g/100ml dietary fiber - Clinutren® 1.5 – see Exhibit 2), it is not clear what level of dietary fiber would be expected to cause gut intolerability. In other words, it is not clear if the results would be expected at a dietary fiber content of 2.6g/100ml despite the particular fiber composition.

Second, the increased fiber supplement (Clinutren® 1.5 Fiber) of Exhibit 1 has not been shown to be commensurate in scope with the rejected to claims. For example, claims 1 and 10-15 are not limited to a fiber content of 2.6 g/100ml (see Exhibit 3) but rather dietary fiber in an amount of more than 2.5g/100ml. Clearly the claimed dietary fiber content is significantly broader than the increased fiber supplement of Exhibit 1 (Clinutren® 1.5 Fiber). It is not clear if all of the compositions recited in claim 1, i.e. dietary fiber in an amount of more than 2.5g/100ml) would be expected to display the same surprising gut tolerability and low viscosity of Clinutren® 1.5 Fiber.

Further, Appellants have not show that the comparison from the study summarized in Exhibit 1 represents the closest prior art. While Appellants show that a composition of the present invention (Clinutren® 1.5 Fiber) is as tolerable and viscous as a similar low fiber composition, the results do not demonstrate that the inventive composition is more tolerable or less viscous than an increased fiber composition of the prior art. In this case, Spivey-Krobath et al. disclose a nutritional composition comprising protein, a source of digestible carbohydrates, and a source of dietary fiber, in an amount of 4g to 50g/200 g of the composition, wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber) or a combination of fructooligosaccharide and acacia gum (soluble fiber). There is nothing on the record demonstrating that the inventive high fiber nutritional composition comprising pea outer fiber is more tolerable or less viscous than any other high fiber comprising nutritional composition, including that of the Spivey-Krobath et al.

Note, while Appellants claim that the inventive nutritional composition displays unexpected low viscosity, Brassart et al. teach that nutritional compositions containing a balance of soluble and insoluble dietary fiber are less viscous. Brassart et al. teach a fiber containing nutritional composition including soluble and insoluble fiber, i.e. pea outer fiber.

Appellants explain that Exhibit 4 describes the synergistic effect that is surprisingly observed between fructooligosaccharides and acacia gum on the bifidogenic affect.

However, it is noted that Spivey-Krobath et al. already disclose a nutritional composition comprising dietary fiber wherein the source of dietary fiber is a combination of fructooligosaccharides and acacia gum. Given Spivey-Krobath et al. disclose a dietary fiber

blend, i.e. fructooligosaccharides and acacia gum, identical to that presently claimed, it is clear that the combination would intrinsically display asserted synergy.

Rejection under 35 U.S.C. 103(a)-

Appellants assert that Spivey-Krobath et al. and Brassart et al. alone or in combination fail to disclose or suggest the nutritional composition of the present invention. Appellants note that Spivey-Krobath et al. fail to disclose a protein content of 4.5g to 6g/100ml, a viscosity of 30-80 mPas or the use of pea outer fiber. Similarly, Appellants note that Brassart et al. teach a protein content below the claimed range, i.e. 3.8g protein/100ml composition, a viscosity outside the claimed range, i.e. about 12 cp, and do not teach the use of pea out fiber.

However, note that while Brassart et al. does not disclose ***all*** the features of the present claimed invention, Brassart et al. is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention. Rather this reference teaches a certain concept, namely a dietary fiber composition comprising a balance of soluble and insoluble fiber (i.e. pea outer fiber) and in combination with the primary reference, discloses the presently claimed invention.

Appellants submit that Spivey-Krobath does not disclose the "identical" composition to the presently claimed composition having certain protein and fiber amounts. Appellants note that the amount of components contained in a composition can greatly affect the viscosity of the composition. Therefore, Appellants argues that it is improper for the Examiner to allege the composition of the cited references have viscosity ranges that are "identical" to the viscosities of the claimed compositions.

First, it is not suggested that the nutritional composition of Spivey-Krobath et al. is "identical" to that presently claimed but rather the nutritional composition of ***modified*** Spivey-Krobath et al.

In summary, **Spivey-Krobath et al.** disclose a nutritional composition comprising (a) 7.0 protein/100 ml composition; (b) a source of digestible carbohydrates; (a) a source of lipids; and (d) a source of dietary fiber wherein the dietary fiber has an energy density of 1.6 kcal/ml, is in an amount of 4g to 50g/300 g of the composition and comprises 70% by weight fructooligosaccharide and 30% by weight inulin (i.e. soluble fiber) or a combination of fructooligosaccharide (i.e. soluble fiber) and acacia gum (i.e. soluble fiber) (Abstract, p.3/L15-17, p.5/L5-6, 35- p.6/L3, p.7/L8-14, p.8/L14-18, p.10/Table 1).

While **Spivey-Krobath et al.** does not explicitly disclose a protein content that overlaps with that presently claimed, the claimed range, i.e. 4.5g to 6.0g/100 ml composition, and the prior art range, i.e. 7.0g/100 ml composition, are close enough that one skilled in the art would have expected them to have the same properties (*see* MPEP 2144.05 – I. Overlap of Ranges).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). **Brassart et al.** teach that the fiber blend comprises 5-30% inulin (soluble dietary fiber), 10-40% fructooligosaccharides (i.e. oligosaccharide, soluble dietary fiber) and 20-50% pea outer fiber (i.e. non-soluble dietary fiber) (C4/L40-44). **Brassart et al.** teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, **Brassart et al.** teach that enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

It would have been obvious to one of ordinary skill in the art to have used a fiber blend including both soluble and insoluble fiber, as taught by **Brassart et al.**, in the nutritional composition of **Spivey-Krobath et al.** for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

Further, given **Spivey-Krobath et al.** disclose the interchangeability of soluble fibers, i.e. inulin and acacia gum in a nutritional composition (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified **Spivey-Krobath et al.** because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Clearly, the nutritional composition of modified Spivey-Krobath et al. is essentially the same or identical to that presently claimed and one of ordinary skill in the art would have expected that the composition would intrinsically display a viscosity in the range presently claimed. There is nothing in the record demonstrating that a nutritional composition comprising 6g/100ml protein would display different properties than one comprising 7g/100 ml.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ELIZABETH GWARTNEY/

Examiner, Art Unit 1781

Conferees:

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781

/Tom Dunn/
Quality Assurance Specialist, TC 1700